

**Food and Drug Administration (FDA)**  
**Center for Drug Evaluation and Research (CDER)**  
***Joint Meeting of the Advisory Committee for Reproductive Health Drugs (ACRHD)***  
***and the Drug Safety and Risk Management Advisory Committee (DSaRM)***

FDA White Oak Campus, Building 31, the Great Room, White Oak Conference Center  
(Rm. 1503), Silver Spring, MD

**March 5, 2013**

**QUESTIONS TO THE COMMITTEE**

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1. **(VOTE)** Does the overall benefit-risk assessment support the continued marketing of calcitonin salmon for the treatment of osteoporosis in women greater than 5 years post menopause?
  - a. Please provide a rationale for your vote and, if applicable, any additional recommendations.
2. **(VOTE)** For calcitonin salmon products under development, should fracture efficacy data be required for approval for treatment or prevention of postmenopausal osteoporosis indications?
  - a. Please provide a rationale for your vote and, if applicable, any additional recommendations.